

*The Philip Morris External Research Program  
(ERP)*

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PMUSA RD&E

PMUSA

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Some have heard - some not  
ERP started August, 2000  
Now going into it's 2nd annual cycle

*18 March 2002*

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Christopher R. Nelson  
Comments and Advice

*K30 3/18/02*

## ***Outline***

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- **Context**
- **Purpose and focus**
- **Process**
- **Progress**

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## Context

- Announcement in August 2000
- Research to support <sup>→ pursuit of Harm Reduction</sup> ~~direction of reduced harm of~~ smoking
- Worldwide
- Credible process
- Independent publication
- Clear attribution of PMUSA funding

Suggestive  
cite exact  
language  
of ERP  
RFP's -  
see  
p. 5

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Is this appropriate  
considering the audience

The MSA of 1998 required disbanding of specific organizations (CTR, CIAR). MSA Section III o.

We are also looking carefully at joint industry activities based on potential antitrust concerns, as well as the MSA's prohibition on agreements to suppress research. MSA Section III q.

### Context: Cornerstones

- Published research agenda, process, SAB members
- Independent process to select proposals for funding
- Publication of data in peer-reviewed scientific journals or at credible scientific conferences encouraged

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USA  
PM is providing:

- research focus
- funding and support

PM is **NOT:**

- directing the program
- involved in project selection

not sure what this means

Contractual language

strongly

ERP(?)

### ***ERP: Purpose***

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To support the highest quality research that

- contributes to fundamental scientific knowledge,
- helps address the concerns of the public health community regarding cigarette smoking, and
- enables Philip Morris to continue its pursuit of product modification(s) or new product design(s) that might reduce the health risk of smoking.

## **ERP: Focus**

### **– Exposure / Biomarkers / Dosimetry**

- Measures of exposure (including methodologies)
- Measures of biological effects

### **– Epidemiological Research**

- Cancer
- Cardiovascular diseases
- Respiratory diseases
- Reproductive, maternal and placental effects
- Combination designs of some or all of the above
- Exposure, biomarkers, and potential mechanisms

*of what (pls clarify)*

### **– Clinical and Model Systems Research, including Validation, and Assays**

- Cancer
- Cardiovascular diseases
- Respiratory diseases
- Reproductive, maternal, and placental effects
- Relevant smoke constituents related to mechanisms

## ***ERP: Focus*** *(cont.)*

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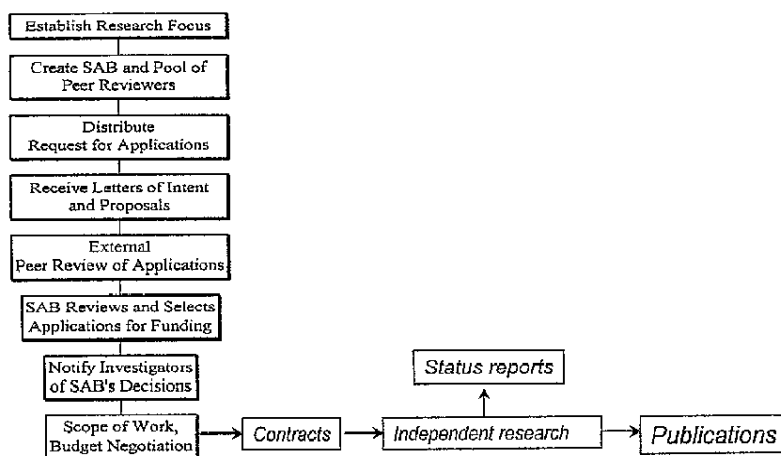
- **Mechanistic Research**

- Molecular reactions related to cell regulation
- Cellular processes
- Disease mechanisms

- **Tobacco Smoke and Smoking Behavior**

- Biochemical and molecular mechanisms
- Nicotine
- Other smoke constituents

## Process



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'Contracts' will change to 'Grants' in 2002

relevant to Audience  
 ? contract? - see current draft template  
 bus. call



## ***Science Advisory Board***

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- **Roy Albert, M.D.** University of Cincinnati Medical Center
- **Curtis Klaassen, Ph.D.** University of Kansas Medical Center
- **Morton Lippmann, Ph.D.** New York University Medical Center
- **Hans Marquardt, M.D.** University of Hamburg Medical Center, Germany
- **Cassandra Smith, Ph.D.** Boston University
- **Mark Utell, M.D.** University of Rochester Medical Center

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## ***Peer reviewers***

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- Approximately 200 external scientists serving as peer reviewers
  - **USA**                      **75%**
  - **International**        **25%**
- From academia, medical institutions, schools of public health, government agencies

### **Progress: Key dates**

**Cycle:** 2001

- RFA advertised and mailed May
- Letter of Intent<sup>+</sup> due Jul.
- Proposals due Aug.
- Notification of awards Feb. 2002

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### ***Progress: 2000 Statistics***

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- Mailing of RFA 2,600
- Advertising in journals Science, Nature
- Number of proposals received 153
  - USA 101
  - Europe 27
  - Asia 18
  - Canada 5
  - South America 2
- Number of proposals selected by SAB for funding 66

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60 contracts signed

For 2002 projected 21 million ~~spending~~

budget of

## **2000 Statistics: Scientific areas**

<b>Cardiovascular</b>	
– CVD epidemiology, physiology, pathology	7
<b>Respiratory diseases</b>	
– COPD, asthma	8
<b>Cancer</b>	
– carcinogenesis, diagnostics, therapy	13
<b>Genetics</b>	
– genomics, genetic susceptibility, genotoxicity	7
<b>Neuroscience</b>	
– neurotoxicity, neuropharmacology, behavior	12
<b>Toxicology</b>	
– Inhalation, mechanisms, biochemical	17
<b>Other</b>	
– e.g. exposure assessment, risk assessment, general epidemiology	<u>2</u>
	66

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*There are three categories  
with two studies - pls clarify.*

## Sample of institutions represented in 2001 ERPP program (?)

- Albert Einstein College of Medicine
- AMC Cancer Research Center
- Case Western Reserve University
- Duke University Medical Center
- Fraunhofer Institute, Germany
- Johns Hopkins School of Medicine
- Karolinska Institute, Sweden
- National Institute of Oncology, Hungary
- New York University Medical Center
- New York University School of Medicine
- Northwestern University Medical School
- Oak Ridge National Laboratory
- Penn State College of Medicine
- Stanford University School of Medicine
- Texas Tech University Health Sciences Center
- Tulane University Medical School
- University of Arizona, College of Public Health
- University of California, Davis, Irvine, Los Angeles, Riverside, and Santa Barbara
- University of Cincinnati Medical Center
- University of Colorado Health Sciences Center
- University of Nebraska Medical Center
- University of Pittsburgh Medical Center
- University of Rochester Medical Center
- University of Texas Medical Branch at Galveston
- University of Virginia

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### Incoming proposals 2000

#### Other reactions:

- Targeted intense intern. Letter and email campaign to discourage peer-reviewers and SAB members from participating ("Action ..")
- Amer. Legacy Foundation
- Soc. Res. Nic. Tob. (SRNT) letter to members not to accept grants
- Current discussions within US Schools of Medicine
- Public health community publications: Remain "skeptical about scientific integrity"; "could be interpreted as soliciting exculpatory programmatic substance" (Hirschhorn et al., Tob. Control 10: 247-252 (2001))
- We make changes → ??

Not sure  
of the  
intent.

Will prompt  
Q- what  
changes?  
Should be  
proposed to  
discuss

Sample of Source of the (?)  
✓ Publications Resulting from  
Philip Morris External Research Program Funding - 2001 (?)

1. Jones, S.; Lo, H.; Simon, S.A., "Nicotinic Receptors in the Peripheral Nervous System". In: Levin, E.D., ed. *Nicotinic Receptors in the Nervous System* CRC Press; 2001: 79-107.
2. Katz, D.B.; Nicolelis, M.A.L.; Simon, S.A., "Electrophysiological Studies of Gustation in Awake Rats". In: Simon, S.A.; Nicolelis, M.A.L., eds. *Methods in Chemosensory Research* Boca Raton; London; New York; London: CRC Press; 2001: 339-357.
3. Katz, D.B.; Simon, S.A.; Nicolelis, M.A.L., "Dynamic and Multimodal Responses of Gustatory Cortical Neurons in Awake Rats". *J. of Neurosci.* **21**: 4478-4489; 2001.
4. Liu, L.; Oortgiesen, M.; Li, L.; Simon, S.A., "Capsaicin inhibits activation of voltage-gated sodium currents in capsaicin-sensitive trigeminal ganglion neurons". *J. Neurophysiol.* **85**: 745-758; 2001.
5. Xu, Z.; Seidler, F.J.; Ali, S.F.; Slikker, W., Jr.; Slotkin, T.A., "Fetal and adolescent nicotine administration: Effects on CNS serotonergic system", *Brain Research*, 914(1-2): 166-178; 2001.
6. Katz, D.B.; Simon, S.A.; Nicolelis, M.A.L., "Taste specific neuronal ensembles from the gustatory cortex of awake rats". *J. of Neurosci.* **22**: 1850-1857; 2002.
7. Liu, L.; Simon, S.A., "Acidic stimuli activates two distinct pathways in taste receptor cells from rat fungiform papillae", *Brain Research*, 923, 58-70, 2001

As of February 2002

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2001 Philip Morris Scientific Publications & Presentations - RD&E

What does this signify

- 30 Publications
- 76 Presentations

• Represented areas include:

- Cigarette design and function
- Metallurgy
- Nicotine
- Ingredients
- Aerosol physics
- Toxicology
- Electrically heated cigarettes
- Smoke chemistry
- Indoor air
- Nitrosamines

Covered? suggest confirming